UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE RE REGISTRATION ELIGIBILITY DECISION DOCUMENT FOR LINDANE

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Please find attached the occupational and residential exposure assessment for lindane

DP BARCODE D254759

Pesticide Chemical Codes: 009001

EPA Reg Nos:

EPA MRID Nos.: 447315-01, 444058-02

PHED: Yes - Version 1.1 Surrogate Tables

**CONTENTS**


EXECUTIVE SUMMARY . . . . . 3
1.0 BACKGROUND . . . . . 4
1.1 Summary of Toxicity Concerns Relating to Occupational Exposures . . . . . 5
1.2 Summary of Use Pattern and Formulations . . . . . 8
1.3 Method and Types of Equipment Used for Mixing/Loading/Applying . . . . . 8
1.4 Incident Reports . . . . . 9

2.0 OCCUPATIONAL EXPOSURES . . . . . 9
2.1 Handler Exposures & Assumptions . . . . . 9
2.1.1 Submitted Studies . . . . . 9
2.1.2 Summary of Occupational Handler Exposures . . . . . 11
2.1.3 Summary of Uncertainties . . . . . 12
2.1.4 Calculations of Exposure . . . . . 14
2.2 Risk From Handler Exposures . . . . . 16
2.2.1 Risk From Handler Exposures . . . . . 17
2.2.2 Summary of MOEs . . . . . 18
2.2.3 Cancer Risks . . . . . 18
2.2.3 Insufficient Data . . . . . 18
REFERENCES . . . . . 22

Appendix A . . . . . 23
Appendix B . . . . . 28

**Executive Summary**

This document presents the occupational exposure assessment for use of lindane. Lindane is the gamma isomer of 1,2,3,4,5,6 hexachlorohexane, an insecticide previously used in many situations but is now restricted to seed treatment only. There are no current registered uses for recreational, residential or other public (non-occupational) settings. All uses other than seed treatment have been deleted.

**Acute Toxicity Categories**

Acute toxicity categories for the technical grade lindane are in Toxicity Category II for oral, Toxicity Category II for dermal, and Toxicity Category II for inhalation. It is in Toxicity Category III for primary eye irritation.

The endpoints used in this document to assess lindane hazards include short-term and intermediate-term dermal and inhalation endpoints. The exposure duration for short-term assessments is 1 to 7 days. Intermediate-term duration is greater than 7 days to several months. Although there is little information to determine what percentage of workers apply for more than 7 days, it is reasonable to believe that typical uses of lindane by commercial seed treatment facilities may encompass an intermediate-term duration. On farm treatments are more likely to be of short-term duration. An oral developmental neurotoxicity study (MRID 45073501) in rats was selected for both dermal assessments. A 90 day inhalation toxicity study (MRID 00255003) was selected for inhalation assessment for all time periods.

In the developmental neurotoxicity study Lindane (99.78% a.i.) was administered to presumed pregnant rats in the diet at concentrations of 0, 10, 50, or 120 ppm (maternal doses of 0.8-0.9, 4.2-4.6, and 8.0-10.5 mg/kg/day during gestation, respectively) from gestation day (GD) 6 through lactation day 10. The dosages during lactation were 1.2-1.7, 5.6-8.3, and 13.7-19.1 mg/kg/day. The developmental neurotoxicity of lindane was evaluated in the $F_1$ offspring (10/sex). The $F_1$ offspring were evaluated for FOB, motor activity, auditory startle response, and learning and memory as well as developmental landmarks such as vaginal perforation and balanopreputial separation, and brain weights and histopathology. The maternal toxicity NOAEL is 50 ppm (5.6 mg/kg/day) based on reduced pup survival, decreased body weights and body weight gains during lactation, increased motor activity, and decreased motor activity habituation. The offspring toxicity NOAEL was 10 ppm (1.2 mg/kg/day). This value was used for both short-term and intermediate-term dermal exposure assessments

In the subchronic inhalation toxicity study (Accession No. 255003), Lindane (99.9% a.i.) was administered by inhalation to groups of 12 male and 12 female Wistar rats at nominal concentrations of 0, 0.02, 0.10, 0.50, or 5.0 mg/m$^3$, 6 h/day for 90 days. The arithmetic mean particle size of the aerosol was 1.11±0.39 ：m (geometric mean was 1.03±1.45 ：m). Additional control and high concentration groups, 12 rats/sex, were treated for 90 days and allowed to recover for 6 weeks before sacrifice. The systemic toxicity NOAELs for short term and intermediate exposure were 0.5 mg/m$^3$

and 0.1 mg/m$^3$ (0.026 mg/kg/day), respectively, based on lesions in the kidney and increased kidney weights.(1).

Exposure data on lindane are limited. Two **handler** exposure studies, one addressing on farm seed treatment (MRID 444058-02) and one addressing commercial seed treatment facilities (MRID 447315-01) were submitted to the Agency. A brief summary of the on farm study is presented in Section 2. A detailed description along with the exposure calculations are presented in Appendix A. The commercial seed treatment study submitted by the registrant has previously been reviewed and used in the Reregistration Eligibility Document for Imazalil (2). The comments and tables from that review are presented in Section 2.

The results of the intermediate-term and short-term handler dermal assessments indicate that the on farm seed treatment provide dermal MOEs less than 100 with the attire worn during the study (long pants, long sleeved shirts, gloves). The short and intermediate assessments, both dermal and inhalation, yielded MOEs of less than 100 for mixing/loading/application during commercial seed treatment at large facilities. All other exposure scenarios provide MOEs greater than or equal to 100 when wearing the clothing used in the study (coveralls over single layer of clothing, gloves for commercial other seed treatment workers) or at **baseline** attire (single layer of clothing, gloves for mixer/loaders) for loading seed for planting or for planting treated seed.

Due to the method of seed treatment HED has determined that soil-incorporated, post-application agricultural exposure is considered to be negligible as long as the soil is not directly contacted. The exception is farmers handling treated seed. An estimate of the inherent risk from handling treated seed was conducted using relatively conservative assumptions. There are no study data available on exposure to lindane residue from treated seed and therefore the exposure was estimated using the unit exposure for handling granular formulations in PHED (3).

## 1.0 BACKGROUND

### Purpose

This document is for use in development of the Reregistration Eligibility Decision Document (RED) for the insecticide lindane and presents a review of the potential human health effects of occupational exposure to lindane.

### Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For lindane, both of these criteria are met.

## 1.1 Summary of Toxicity Concerns Relating To Occupational Exposures

### Acute Toxicology Categories

Table 1 presents the acute toxicity categories as outlined in the Report of the Hazard Identification Assessment Review Committee (1).

**Table 1: Acute Toxicity Categories for Lindane (Technical)**

| STUDY TYPE | MRID | CATEGORY | RESULT |
|---|---|---|---|
| 81-1 Acute oral | 00049330 | II | $LD_{50}$ 88 mg/kg - males<br>91 mg/kg - females |
| 81-2 Acute dermal | 00109141 | II | $LD_{50}$ 1000 mg/kg - males<br>900 mg/kg - females |
| 81-3 Acute inhalation | Acc. 263946 | III | $LC_{50}$ 1.56 mg/L both sexes |
| 81-4 Eye irritation | Acc. 263946 | III | PIS = 0.6 no corneal involvement<br>irritation cleared after 24 hours |
| 81-5 Dermal irritation | Acc. 263946 | IV | PIS = 0 not an irritant |
| 81-6 Dermal sensitization | Acc. 263946 | NA | not a sensitizer |

### Other Endpoints of Concern

The Report of the Hazard Identification Assessment Review Committee (HIARC) for lindane, (1) indicates that there are toxicological endpoints of concern for lindane. The endpoints used in assessing the risks for lindane are presented in Table 2.

## Table 2: Endpoints for Assessing Occupational Risks for Lindane

| EXPOSURE SCENARIO | DOSE (mg/kg/day) | ENDPOINT | STUDY TYPE/ MRID |
|---|---|---|---|
| Acute Dietary- general population | NOAEL= 6 mg/kg<br>UF = 100 | LOAEL is 20 mg/kg based on increased grip strength, increased Motor Activity | Acute Neurotoxicity in Rats/<br>44769201 |
| Acute Dietary-females 13-50 | NOAEL= N/A<br><br>UF = N/A | No relevant single exposure endpoint was identified. | N/A |
| **Acute RfD (Gen. Pop.) = 0.06 mg/kg/day Acute RfD (Females 13-50) = N/A** | | | |
| Chronic Dietary | NOAEL=10 ppm<br>(0.47 mg/kg/day)<br><br>UF = 100 | LOAEL is 100 ppm (4.81 mg/kg/day) periacinar hepatocyte hypertrophy, increased liver/spleen weight, increased platelets | Chronic Feeding and Carcinogenicity in Rats<br>41094101<br>41853701<br>42891201 |
| | **Chronic RfD = 0.0047 mg/kg/day** | | |
| | Cancer Risk [3] | **$Q_1$* = To be determined** | |
| Short-Term [1]<br>(Dermal) | Oral NOAEL= 10 ppm<br>(1.2 mg/kg/day) | LOAEL is 50 ppm based on reduced pup survival, decreased body weights and body weight gains during lactation, increased motor activity, and decreased motor activity habituation. | Developmental Neurotoxicity Study in Rats<br>45073501 |
| Intermediate-Term [1]<br>(Dermal) | Oral NOAEL= 10 ppm<br>(1.2 mg/kg/day) | LOAEL is 50 ppm based on reduced pup survival, decreased body weights and body weight gains during lactation, increased motor activity, and decreased motor activity habituation. | Developmental Neurotoxicity Study in Rats<br>45073501 |
| Long-Term [1]<br>(Dermal) | Oral NOAEL=10 ppm<br>(0.47 mg/kg/day) | LOAEL is 100 ppm (4.81 mg/kg/day) periacinar hepatocyte hypertrophy, increased liver/spleen weight, increased platelets | Chronic Feeding and Carcinogenicity in Rats<br>41094101<br>41853701<br>42891201 |
| Dermal Absorption Factor = 10% | | | |
| Short Term [1]<br>(Inhalation) | 0.5 mg/m$^3$<br>(0.13 mg/kg/day) | based on clinical signs (diarrhea, piloerection) seen at day 14 and continuing for 20 days | 90-Day Inhalation Toxicity<br>00255003 |
| Intermediate Term [1]<br>(Inhalation) | 0.1 mg/m$^3$<br>(0.026 mg/kg/day) | 0.5 mg/m$^3$ (0.13 mg/kg/day) micro lesions in kidney, increased kidney weight | 90-Day Inhalation Toxicity<br>00255003 |

| Table 2: Endpoints for Assessing Occupational Risks for Lindane | | | |
|---|---|---|---|
| EXPOSURE SCENARIO | DOSE (mg/kg/day) | ENDPOINT | STUDY TYPE/ MRID |
| Acute Dietary- general population | NOAEL= 6 mg/kg<br>UF = 100 | LOAEL is 20 mg/kg based on increased grip strength, increased Motor Activity | Acute Neurotoxicity in Rats/ 44769201 |
| Long Term [2] (Inhalation) | N/A | N/A | N/A |

[1] Since an oral NOAEL was selected, the dermal absorption factor (10%) should be used in route-to-route extrapolation.

[2] Exposure thru this route for this duration is not expected

[3] The Cancer Risk will be re-evaluated upon receipt of the Mouse Carcinogenicity Study in December 2000

## 1.2 Summary of Use Patterns and Formulations

The only use remaining for lindane is for seed treatment. The use closure memorandum (4) allows the seed treatment of the following crops: barley, broccoli, Brussels sprouts, cabbage, cauliflower, corn, lettuce, oats, radishes, rye, sorghum, spinach, and wheat. The crops and application rates are presented in Table 3. Wheat was used as a representative crop for all other seeds treated with lindane because of the relatively large farm size, application rate, and nature of the product treated.

| **Table 3. Summary of Application Rates for Seed Treatment Using Lindane on Various Crops.** | | |
|---|---|---|
| **Commodity** | **Formulation/Reg. No.** | **Use Rate** |
| barley | | 0.0375 lb ai/100 pound seed |
| broccoli | EC (554-144) | 0.11925 lb ai/100 pound seed |
| Brussels sprouts | EC (554-144) | 0.11925 lb ai/100 pound seed |
| cabbage | EC (554-144) | 0.11925 lb ai/100 pound seed |
| cauliflower | EC (554-144) | 0.11925 lb ai/100 pound seed |
| corn | dust (19713-262)<br>EC (71096-2) | 0.125 lb ai/bushel seed<br>0.125 lb ai/100 pound seed |
| lettuce | dust (34704-658, 19713-262, 10107-121) | 0.0625 lb ai/100 pound seed |
| oats | 7501-38, 10107-121 | 0.03125 lb ai/100 pound seed |
| radish | FlC (7501-16, 7501-34) | 0.03232 lb ai/100 pound seed |

| | | |
|---|---|---|
| rye | 19713-401 554-144 19713-387 | 0.032813 lb ai/100 pound seed |
| sorghum | 42056-15 | 0.0628 lb ai/100 pound seed |
| spinach | dust (7501-38, 34704-653, 34704-658, 19713-262, 34704-658, 42056-14, 10107-121, 66330-19) | 0.0625 lb ai/100 pound seed |
| wheat | dust, 2935-492 | 0.042578 lb ai/100 pound seed |

### 1.3 Method and Type of Equipment Used for Mixing/Loading/Applying

The flowable concentrate, and emulsifiable concentrate formulations all require mixing with water to the label-specified dilution. This is usually performed by scooping or pouring the formulation into a mixing tank, often of 100 gallons or more in capacity, with mechanical agitation to keep the resulting emulsion homogenized and prevent variations in application strength. Smaller amounts may be handled using a tiller-planter (or seed drill)-mounted system. Large commercial operations, may have mechanical, automated, metered pumps which require only connecting the formulation to the pump. Again, small seed treatment operations, such as seed box (or "hopper box") mixing, may be done by pouring small amounts in to a mixing device before planting the seeds in to the soil.

**Timing and Frequency of Application**

Generally, seed will be treated on an as needed basis. However, it is industry practice only to treat enough seeds as are needed to be used that season.

### 1.4 Incident Data

No information regarding seed treatment incidents is available at this time.

## 2.0 OCCUPATIONAL EXPOSURES

### 2.1 Handler Exposures & Assumptions

HED has determined that there are potential exposures to mixers, loaders, applicators, or other handlers during usual use-patterns associated with lindane. Based on the use patterns and potential exposures described above, 5 major exposure scenarios were identified to represent the extent of lindane uses: (1) mixing/loading/application of formulations for on-farm seed treatment, (2) mixing/loading and applying liquid with commercial seed-treatment equipment, (3) bagging and otherwise handling treated seeds, (4) mixing/loading of treated seed for planting, (5) planting treated

seeds.

### 2.1.1 Submitted Studies

Mixer/loader/applicator exposure data for lindane were required since one or more toxicological criteria had been triggered. Requirements for applicator exposure studies are addressed by Series 875 Group A (formerly Subdivision U of the Pesticide Assessment Guidelines). Two exposure studies, one addressing commercial seed treatment and the other on-farm treatmen have been providedt. These commercial seed treatment study has been evaluated by the Agency and used in another Reregistration Eligibility Document (2). A summary of an on-farm treatment exposure study is presented below. A detailed review, along with exposure calculations is presented in Appendix A. In the case of mixing/loading and planting of treated seed, data from PHED V1.1 were used for exposure estimation. It was assumed that exposures from treated seed would resemble those from mixing/loading or application of granular formulations.

**MRID No. - 447315-01.** Review of assessment of worker exposure to Commercial Seed Treatment in Seed Treating Plants (Vitavax® 3RS flowable- Canola-Alberta, Canada).
During this study, workers were monitored for dermal and inhalation exposure during the loading, application, bagging, sewing, and stacking of Canola seeds treated with Vitavax ® RS Flowable. In support of the reregistration process for imazalil, UniRoyal submitted a worker exposure study for review by EPA. The test substance is a water-based flowable seed treatment formulation containing three active ingredients, Lindane (48.7 percent), Thiram (6.43 percent), and Carboxin (3.34 percent).

This study was conducted at three seed-treatment plants in Alberta, Canada. The three facilities are considered representative of large, medium and small seed-treating operations and all sites used different seed treatment equipment. A total of nine replicates were monitored in the study. (The guidelines suggests that at least 15 replicates be examined per study). Four of the replicates were categorized as loader/applicators and the remaining five workers were categorized as seed handlers. The sampling period consisted of one 8-hour work day. The maximum application rate for seed treatment of approximately 562 ml (19oz) of formulated product per 25 kg (55.31lb) seed was applied at each site. Treated seed samples were collected twice at each test site to verify the actual application rate. The study is only partially compliant with OPPTS 875 Group A test guidelines.

**Study Results**

The geometric mean values obtained from this study had the lowest standard deviation and are presented in Table 4.

| Table 4 : Summary of the Exposure values of Canola Seed Treatment to Lindane in Canada | | |
|---|---|---|
| Scenario | mg/lb ai (no gloves) | mg/lb ai (gloves) |

| | | |
|---|---|---|
| Loader/Applicator (Dermal) | 0.36 | 0.063 |
| Seed Handler (Dermal) | 0.015 | 0.0022 |
| Loader/Applicator (Inhalation) | 0.0014 | 0.0014 |
| Seed Handler (Inhalation) | 0.00018 | 0.00018 |

On-farm seed treatment is probably restricted to smaller farms because of the greater time, labor, and equipment requirements as compared to those from the use of commercially treated seed. The grain is usually not stored but planted after treatment in the planter hoppers. The only applicable study available to HED was submitted by Rhone-Poulenc, Inc. A detailed description of the study and the calculations for exposure assessment are presented in Appendix A. A brief description is presented below.

**MRID No. 444058-02 Fenske, R. A. Reregistration of Lindane Technical Case No. 0315, Chemical No. 9001. Worker Exposure to Lindane During Manual Seed Treatment.**

Dermal and respiratory exposures of 4 male workers with prior experience during the manual treatment of winter wheat at a commercial wheat farm in South Dakota. The operations are considered to be representative of manual seed treatments in the Midwest. A dust formulation containing 18.75 percent lindane, packaged in 10 lb bags was applied at the label rate of 2 ounces per bushel of seed. A total of 720 bushels of seed were treated. The treatment procedure involved the addition of grain to a 4 compartment, 12 bushel grain drill. The label instructions indicate the user is to fill the drill box half full of seed and add half of the formulation. The seed and formulation are then mixed with a stick. The rest of the grain is then added and the procedure repeated. After thorough mixing the seed was removed by a vacuum. Workers monitored in this study did not participate in the vacuuming procedure.

Each mixing consisted of the application of 24 oz (680 g) of the formulation to 12 bushels of grain. A plastic scoop, cut from a plastic bottle and determined to hold 12 oz of formulation, was used to remove the powder from the bag. The scoop was used to spread the formulation evenly over the seed.

Each replicate consisted of five mixings conducted by each of the four workers, the mixing activity lasting 4-6 minutes. The mixing periods averaged 24 minutes and were separated by 10-20 minute breaks. This was considered to be equal to one "work period". During this time a worker handled 120 oz of formulation or 1.4 lb of active ingredient. Each volunteer performed the tasks three times (total of 60 mixings), yielding a total of 12 work periods. During treatments the workers wore the label required long sleeve shirt, long pants, Nitrile gloves, a baseball cap, and a pesticide respirator. All clothing was new and/or prewashed to avoid confounding analytical problems. The workers did not remove their gloves during the procedure but did during breaks.

Dermal exposures were monitored using gauze dosimeters encased in an envelope with a 5.6 cm diameter circle exposed to the environment (25 $cm^2$ total area). Dosimeters were either attached to the

clothing or taped to the skin on the chest, back, shoulders, forearms, upper legs, or lower legs. Two sets of dosimeters were used, one outside the clothing and the other inside the work garments. Care was taken to avoid overlap of the dosimeters, which could confound the results of the inner monitors. Dermal exposure of the hands was monitored by hand wash with 10 percent isopropanol in distilled water. Respiratory exposure was monitored using calibrated battery powered pumps attached to the belt. Dermal Exposure was 9.4 mg/lb ai and the inhalation exposure was 0.0016 mg/lb ai.

### 2.1.2 Summary of Occupational Handler Exposures

Table 5 presents the exposure scenarios, application rates, and amount potentially handled that have been used for the exposure calculations. These are restricted to canola for commercial seed treatment and wheat for on-farm treatments as representative of typical applications. Exposures for handling treated seed before planting and planting treated seed use parameters for wheat only, as a representative crop. Therefore, the rates/seed types presented in Table 5 are not all conclusive and no attempt has been made to assess a range of application rates to ensure that all use rates and exposure scenarios are represented.

A series of tables (4), derived from PHED V1.1, was used to address the exposure scenarios not monitored by the registrant. PHED was designed by a Task Force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and members of the American Crop Protection Association. PHED is a software system consisting of two parts- a database of measured exposure values and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains over 1,700 monitored individuals (i.e., replicates).

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest, upper arm) is categorized as normal, lognormal, or “other” (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the

arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The estimates from the surrogate guide were obtained assuming that the loading and planting of treated seed would resemble those from the mixing/loading and application of granular formulations. Storage data for lindane on grain indicate that there would be little breakdown of the material on this medium over the useful storage time of treated grain (5). The unit exposures for mixing/loading and application of granular formulations are presented in Table 6.

### 2.1.3 Summary of Uncertainties

The assumptions and uncertainties are identified below to be used in risk management decisions:

- *Application Rates:* Based on wheat for on farm treatment and canola for commercial seed treatment. Other types of seed may have slightly different rates but these differences are unlikely to appreciably alter the exposure/risk assessment.

- *Amount Handled:* For commercial seed treatment the amounts handled are assumed to be equal to the amounts handled at the facilities used in the study described above. On farm treatment exposures were estimated assuming that enough seed could be treated and planted for 100 acres per day at a rate of 120 pounds of seed per acre.

- *Unit Exposures:* The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. These evaluation criteria and the caveats specific to each exposure scenario are summarized in Appendix A Table A5. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases.

- *Data Gaps*: Although a study addressing commercial seed treatment was submitted and used for exposure assessment, it was of poor quality. It is also HED's understanding that current technology is more automated and may yield lower exposures than those from the submitted study. HED has no data with which to revise the commercial seed treatment assessment at this time. Other seed treatment studies and reports of these studies are currently undergoing review by other HED personnel. If warranted, an addendum to this document will be provided upon completion of those

reviews.

| Table 5: Exposure Variables for Uses of Lindane | | | | | |
|---|---|---|---|---|---|
| Exposure Scenario (Scenario #) | Are Chemical Specific Monitoring Data Available? | Are PHED Data Available? | Application Rates (lb ai/amt of seed) | Daily lb Seed Treated/Handled | Lb ai Handled/day |
| Applicator/Handler Exposure | | | | | |
| (1) mixing/loading/planting of dry formulations for on farm treatment | Yes MRID #44440585-02 | No | 0.023 lb ai/bushel (60 lbs seed) for wheat | 12000 lbs seed, see Appendix A) | 4.7[a] |
| (2) mixing/loading and applying liquid with a commercial seed-treatment equipment | Yes Analysis from Imazalil RED (2) MRID #447315-01 | No | 0.04 lb ai/lb seed treated | Small: 22000 | 8.8[b] |
| | | | | Medium: 22000 | 8.8 |
| | | | | Large: 165000 | 66 |
| (3) handler for commercial seed-treatment equipment (i.e. bagging and stacking) | Yes Analysis from Imazalil RED (2) MRID #447315-01 | No | 0.04 lb ai/lb seed treated | Small: 22000 | 8.8[b] |
| | | | | Medium: 22000 | 8.8 |
| | | | | Large: 165000 | 66 |
| (4) loading treated seed for planting (assuming commercially treated seed) | No | Yes | 0.023 lb ai/bushel (60 lbs seed) for wheat | 30000 lbs[c] | 11.5 |
| (5) Planting treated seed (assuming commercially treated seed), Enclosed cab | No | Yes | 0.023 lb ai/bushel (60 lbs seed) for wheat | 30000 lbs | 11.5 |
| (5) Planting treated seed (assuming commercially treated seed), Open cab | No | Yes | 0.023 lb ai/bushel (60 lbs seed) for wheat | 30000 lbs | 11.5 |

[a] Data are available from on farm treatment study (discussed in text above, see Appendix A)

[b] Data are from commercial seed treatment study adjusted for application rate of 0.04 lbs ai per 100 lbs seed(Table 3)

lb ai/day (large facility) = 0.04 lb ai/100 lb seed x 165000 lbs seed/day = 66 lb ai/day

lb ai/day (medium or small facility) = 0.04 lb ai/100 lb seed x 22000 lbs seed/day = 8.8 lb ai/day

[c] Daily amount treated based on HEDs estimates of acreage that would be reasonably expected to be planted in a day for commercially treated seed. The acres per day assumed 120 lbs. of wheat per acre, planting an average of 250 acres of wheat per day (2).

### 2.1.4 Calculations of Exposure

The potential daily dermal exposure was calculated using the following formula:

Potential daily dermal exposure is calculated using the following formula:

$$\text{Daily Dermal Exposure}\left(\frac{\text{mg AI}}{\text{Day}}\right) = \text{Dermal Unit Exposure}\left(\frac{\text{mg AI}}{\text{lb AI}}\right) \cdot \text{Amt. Handled}\left(\frac{\text{lb AI}}{\text{Day}}\right)$$

Potential daily inhalation exposure is calculated using the following formula:

$$\text{Daily Inhalation Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right) =$$
$$\text{Unit Exposure}\left(\frac{\mu\text{g ai}}{\text{lb ai}}\right) \times \text{Conversion Factor}\left(\frac{1\text{mg}}{1{,}000\ \mu\text{g}}\right) \times \text{Amount Handled}\left(\frac{\text{lb ai}}{\text{Day}}\right)$$

The daily dermal and inhalation doses were calculated using a 70 kg body weight using the following formulas:

$$\text{Daily Inhalation Dose}\left(\frac{\text{mg ai}}{\text{kg/day}}\right) = \text{Daily Inhalation Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right) \times \left(\frac{1}{\text{Body Weight (kg)}}\right)$$

$$\text{Daily Dermal Dose}\left(\frac{\text{mg ai}}{\text{Kg/Day}}\right) = \text{Daily Dermal Exposure}\left(\frac{\text{mg ai}}{\text{Day}}\right) \times \left(\frac{1}{\text{Body Weight (Kg)}}\right) \times 0.10\ \text{Dermal Absorption Factor}$$

**Table 6. Unit Exposures from the PHED Surrogate Guide for Workers Mixing/Loading and Applying Granular Formulations Using Agricultural Equipment.**

| Activity | Clothing/Cab Scenario | Unit Exposure (mg/lb ai) | | Confidence |
|---|---|---|---|---|
| | | Dermal | Inhalation | |
| Application by Solid Broadcast Spreader Application (Surrogate for Planting) | Open Cab, Single Layer of Clothing, No Gloves | 0.0099 | 0.0012 | Low |
| | Open Cab, Single Layer of Clothing, Gloves | No Data | 0.0012 | Low (not used for risk assessment) |
| | Closed Cab, Single Layer of Clothing, No Gloves | 0.0021 | 0.00022 | High |
| | Closed Cab, Single Layer of Clothing, Gloves | 0.0020 | 0.00022 | High |
| Mixing/Loading | Single Layer of Clothing, No Gloves | 0.0084 | 0.0017 | Dermal Low, Inhalation High (not used for risk assessment) |
| | Single Layer of Clothing, Gloves | 0.0069 | 0.0017 | Dermal Medium, Inhalation High |
| | Coveralls over Single Layer of Clothing, Gloves | 0.0034 | 0.0017 | Dermal Low, Inhalation High (not used for risk assessment) |

## 2.2 Risk From Handler Exposures

EPA calculated the potential risk to persons from handler exposures and planting of treated seed using the daily dermal exposure scenarios identified in the exposure section.

Potential dermal and inhalation daily exposures for occupational handlers were calculated using the following formulas (10 percent dermal absorption was assumed):

$$\textit{Daily Inhalation Exposure}\left(\frac{\textit{mg ai}}{\textit{day}}\right) =$$
$$\textit{Unit Exposure}\left(\frac{\mu\textit{g ai}}{\textit{lb ai}}\right) \times \textit{Conversion Factor}\left(\frac{1\ \textit{mg}}{1{,}000\ \mu\textit{g}}\right) \times \textit{Use Rate}\left(\frac{\textit{lb ai}}{\textit{A}}\right) \times \textit{Daily Acres Treated}\left(\frac{\textit{A}}{\textit{day}}\right)$$

The inhalation and dermal daily doses were calculated using the following formulas:

$$\textit{Daily Dermal Exposure}\left(\frac{\textit{mg ai}}{\textit{day}}\right) = \textit{Unit Exposure}\left(\frac{\textit{mg ai}}{\textit{lb ai}}\right) \times \textit{Use Rate}\left(\frac{\textit{lb ai}}{\textit{A}}\right) \times \textit{Daily Acres Treated}\left(\frac{\textit{A}}{\textit{day}}\right)$$

$$\textit{Daily Inhalation Dose}\left(\frac{\textit{mg ai}}{\textit{kg/day}}\right) = \textit{Daily Inhalation Exposure}\left(\frac{\textit{mg ai}}{\textit{day}}\right) \times \left(\frac{1}{\textit{Body Weight (kg)}}\right) \times 1\ (100\%)$$

$$\textit{Daily Dermal Dose}\left(\frac{\textit{mg ai}}{\textit{kg/Day}}\right) = \textit{Daily Dermal Exposure}\left(\frac{\textit{mg ai}}{\textit{Day}}\right) \times \left(\frac{1}{\textit{Body Weight (kg)}}\right) \times 0.1\ (10\%)$$

### 2.2.1 Risk From Handler Exposures

Margins of Exposure (MOEs) were calculated for handlers for short-term (one to seven days) and intermediate-term (one week to several months) durations for both dermal and inhalation exposures.

The MOEs were calculated using the following formulas:

$$\textit{MOE} = \frac{\textit{NOAEL}\left(\frac{\textit{mg}}{\textit{kg/day}}\right)}{\textit{Dermal Daily Dose}\left(\frac{\textit{mg}}{\textit{kg/day}}\right)}$$

$$MOE = \frac{NOAEL\left(\frac{mg}{kg/day}\right)}{Inhlation\ Daily\ Dose\left(\frac{mg}{kg/day}\right)}$$

### 2.2.2 Summary of MOEs

The daily exposures, resulting short and intermediate term MOEs are presented in Table 7. The exposure scenario descriptions are presented in Table 8. The results of the **short-term** dermal exposure duration indicate that the MOEs range from 5.2 for on farm seed treatment to 34000 for the planting of treated seed . A total of 9 dermal and inhalation MOEs were calculated for the various scenarios. Based on the level of protection used in the studies, all of the MOEs for the application portion of seed treatment were less than 100. All other dermal MOEs were above 100. Inhalation MOEs for workers other than applicators for commercial treatment and seed handlers at large facilities are greater than 100.

The results of the **intermediate-term** dermal exposure duration indicate that the dermal MOEs range from 5.5 for applicators at large seed treating facilities to 1200 for seed handlers at small to medium facilities . Intermediate MOEs were not calculated for on farm application, loading of treated seed for planting, and planting of treated seed since these tasks would not occur over the time periods defined by this interval (greater than 7 days to several months).

### 2.2.3 Cancer Risks

Although the Agency has identified a potential cancer concern for lindane, existing mouse oncogenicity studies are judged to be inadequate (1). Another cancer study in the mouse is was received in December 2000. No cancer risk is calculated in this document. An addendum to this document, addressing cancer risks, will be generated upon review of that study.

### 2.2.4 Insufficient Data

Although a study addressing commercial seed treatment was submitted and used for exposure assessment, it is of poor quality. HED has no data with which to revise the commercial seed treatment assessment to account for more advanced technology at this time. As stated earlier, other studies are undergoing review by HED personnel at this time and may alter our estimate of exosure.

| Table 7: Daily Exposures, Short Term MOEs and Intermediate MOEs During Seed Treatment and Planting of Treated Seed. | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Exposure Scenario (Scenario #) | Range of Application Rates ( lb ai/100 lbs seed OR Lb/A) | Amount Handled per Day (lbs ai) | Unit Exposure (mg/lb ai) | | Daily Exposure (mg/kg/day) | | Short-Term MOEs | | Intermediate,- Term MOEs | |
| | | | Dermal | Inhalation | Dermal | Inhalation | Dermal | Inhalation | Dermal | Inhalation |
| | | | | | | | | | | |
| Mixing/loading/planting dry formulation for on farm seed treatment (1) | 0.038 | 4.7 | 9.4[c] | 0.0016 | 0.063 | 0..00012 | 19 | 1200 | Intermediate-term not applicable for this scenario | |
| Mixing/loading/application of liquid formulation for commercial seed treatment (2) | 0.04 | 8.8 (Small facility, 22000 lbs seed/day ) | 0.063[d] | 0.0014 | 0.00081 | 0.00018 | 1500 | 2800 | 1500 | 144 |
| | | 8.8 (Medium facility, 22000 lbs seed/day ) | 0.063[d] | 0.0014 | 0.00081 | 0.00018 | 1500 | 2800 | 1500 | 144 |
| | | 66 (Large Facility, 165000 lbs seed/day ) | 0.063[d] | 0.0014 | 0.0059 | 0.0013 | 200 | 380 | 200 | 20 |
| Seed Handler for commercial seed treatment (3) | 0.04 | 8.8 (Small facility, 22000 lbs seed/day ) | 0.0022[d] | 0.00018 | 0.00002 8 | 0.000023 | 43000 | 5700 | 43000 | 4300 |

| Table 7: Daily Exposures, Short Term MOEs and Intermediate MOEs During Seed Treatment and Planting of Treated Seed. | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Exposure Scenario (Scenario #) | Range of Application Rates ( lb ai/100 lbs seed OR Lb/A) | Amount Handled per Day (lbs ai) | Unit Exposure (mg/lb ai) | | Daily Exposure (mg/kg/day) | | Short-Term MOEs | | Intermediate,- Term MOEs | |
| | | | Dermal | Inhalation | Dermal | Inhalation | Dermal | Inhalation | Dermal | Inhalation |
| | | 8.8 (Medium facility, 22000 lbs seed/day ) | 0.0022[d] | 0.00018 | 0.000028 | 0.000023 | 43000 | 5700 | 43000 | 4300 |
| | | 66 (Large Facility, 165000 lbs seed/day ) | 0.0022[d] | 0.00018 | 0.00021 | 0.0002 | 5700 | 760 | 5700 | 150 |
| Loading treated seed for planting (4) | 0.038 | 11.5 | 0.0069[c] | 0.0017 | 0.00011 | 0.00028 | 11000 | 460 | Intermediate-term not applicable for this scenario | |
| Planting treated seed (5), Enclosed Cab | 0.038 | 11.5 | 0.0021 | 0.00022 | 0.000014 | 0.000015 | 34000 | 3600 | Intermediate-term not applicable for this scenario | |
| Planting treated seed (6), Open Cab, No gloves | 0.038 | 11.5 | 0.0099 | 0.0012 | 0.00016 | 0.00020 | 7500 | 650 | Intermediate-term not applicable for this scenario | |

[a] Daily Exposure (mg/kg/day) =mg/lb ai x lb ai/day x 0.1 (Absorption factor) ÷ 70 kg bw

[b] Daily Exposure (mg/kg/day) =mg/lb ai x lb ai/day ÷ 70 kg bw

[c] Assumes single layer of clothing and gloves

[d] Assumes coveralls over single layer of clothing and gloves

[e] Assumes closed cab, single layer of clothing and no gloves

Table 8. Exposure Scenario Descriptions for the Use of Lindane.

| Exposure Scenario (Scenario #) | Data Source | Standard Assumptions[a] | Comments[b] |
|---|---|---|---|
| Mixing/loading /planting dry formulation for on farm seed treatment (1) | Rhone-Poulenc Data MRID # 444058-02 | Assumes enough seed treated and planted for 100 Acres per day | All data were for gloved hands; (see study, Appendix A. ) |
| Mixing/loading/application of liquid formulation for commercial seed treatment (2) | Uniroyal Data MRID # 447305-01 | 22000 lbs of seed per day at small and medium facilities; 165000 lbs at large facilities | See study review; based on geometric mean of data and amounts of seed from study data |
| Seed Handler for commercial seed treatment (3) | Uniroyal Data MRID # 447305-01 | 22000 lbs of seed per day at small and medium facilities; 165000 lbs at large facilities | See study review; based on geometric mean of data and amounts of seed from study data |
| Loading treated seed for planting (4) | PHED Surrogate Table | Assumes 250 acres are planted per day at 120 lbs of seed per acre | See Table 6 for data quality |
| Planting treated seed (5), Commercially treated seed | PHED Surrogate Table | Assumes 250 acres are planted per day at 120 lbs of seed per acre | See Table 6 for data quality |
| Planting treated seed (6), Commercially treated seed | PHED Surrogate Table | Assumes 250 acres are planted per day at 120 lbs of seed per acre | See Table 6 for data quality |

a All *Standard Assumptions* are based on an 8-hour work day as estimated by HED.

b All handler exposure assessments in this document are based on the "Best Available" data as defined by the PHED SOP for meeting Subdivision U Guidelines (i.e., completing exposure assessments). Best available grades are assigned to data as follows: matrices with A and B grade data (i.e., Acceptable Grade Data) and a minimum of 15 replicates; if not available, then grades A, B and C data and a minimum of 15 replicates; if not available, then all data regardless of the quality (i.e., All Grade Data) and number of replicates. High quality data with a protection factor take precedence over low quality data with no protection factor. Generic data confidence categories are assigned as follows:

High = grades A and B and 15 or more replicates per body part

Medium = grades A, B, and C and 15 or more replicates per body part

Low = any run that included D or E grade data or has less than 15 replicates per body part

REFERENCES


1) Lindane - Report of the Hazard Identification Assessment Review Committee, July 27, 2000.

2) Memorandum from S. Tadayon (CEB1) to A. Khasawinah (RRB4) titled "Occupational and Residential Exposure Assessment and Recommendations for the Registration Eligibility Decision Document for Imazalil", dated April 15, 2,000.

3) EPA (1998) Surrogate Exposure Guide, Estimates of Worker Exposure from the Pesticide Handler Exposure Database Version 1.1

4) Memorandum from M. Howard (SRRD) to Lindane RED Team Members titled "Final Lindane Use Closure Memo" dated May 17, 2000 (EMAIL).

5) Saha, J.G. and Y.W. Lee (1974) Degradation of Lindane $^{14}C$ by Wheat Grain. Environmental Letters, 7(4), 359-366.


cc: Lindane file (009001)
Correspondence file

**APPENDIX A. MANUAL SEED TREATMENT (at farm):**

**CITATION: Fenske, R.A., A.M. Blacker, S.J. Hamburger, and G.S. Simon (1990) Worker Exposure and Protective Clothing Performance During Manual Seed Treatment with Lindane. Arch. Environ. Contam. Toxicol. 19, 190-196.**

**Fenske, R. A. Reregistration of Lindane Technical Case No. 0315, Chemical No. 9001. Worker Exposure to Lindane During Manual Seed Treatment. MRID No. 444058-02**

Dermal and respiratory exposures of 4 male workers with prior experience were monitored during the manual treatment of winter wheat at a commercial wheat farm in South Dakota. The operations are considered to be representative of manual seed treatments in the midwest. A dust formulation containing 18.75 percent lindane, packaged in 10 lb bags was applied at the label rate of 2 ounces per bushel of seed. A total of 720 bushels of seed were treated. The treatment procedure involved the addition of grain to a 4 compartment, 12 bushel grain drill. The label instructions indicate the user is to fill the drill box half full of seed and add half of the formulation. The seed and formulation are then mixed with a stick. The rest of the grain is then added and the procedure repeated. After thorough mixing the seed was removed by a vacuum. Workers monitored in this study did not participate in the vacuuming procedure.

Each mixing consisted of the application of 24 oz (680 g) of the formulation to 12 bushels of grain. A plastic scoop, cut from a plastic bottle and determined to hold 12 oz of formulation, was used to remove the powder from the bag. The scoop was used to spread the formulation evenly over the seed.

Each replicate consisted of five mixings conducted by each of the four workers, the mixing activity lasting 4-6 minutes. The mixing periods averaged 24 minutes and were separated by 10-20 minute breaks. This was considered to be equal to one "work period". During this time a worker handled 120 oz of formulation or 1.4 lb of active ingredient. Each volunteer performed the tasks three times (total of 60 mixings), yielding a total of 12 work periods. During treatments the workers wore the label required long sleeve shirt, long pants, Nitrile gloves, a baseball cap, and a pesticide respirator. All clothing was new and/or prewashed to avoid confounding analytical problems. The workers did not remove their gloves during the procedure but did during breaks.

Dermal exposures were monitored using gauze dosimeters encased in an envelope with a 5.6 cm diameter circle exposed to the environment (25 $cm^2$ total area). Dosimeters were either attached to the clothing or taped to the skin on the chest, back, shoulders, forearms, upper legs, or lower legs. Two sets of dosimeters were used, one outside the clothing and the other inside the work garments. Care was taken to avoid overlap of the dosimeters, which could confound the results of the inner monitors. Surface areas were assumed to be those outlined in the Agency's Guidance (OPPTS 875 Group A test guidelines, formerly Subdivision U).

Dermal exposure of the hands was monitored by hand wash with 250 mL of 10 percent isopropanol in distilled water. A plastic bag was wrapped around the wrist and the bag shaken for about 30 seconds. This procedure was repeated 3 times, resulting in a pooled volume of 750 mL for each hand. Hand rinses

were conducted for each hand immediately prior to the exposure period and again immediately after. Approximately 75 mL was transferred to a glass jar for storage.

Respiratory exposure was monitored using calibrated battery powered pumps attached to the belt with a 37 mm fiberglass filter attached to the collar in the breathing zone. The flow rate was approximately 2 liters per minute.

Dermal dosimeters and air filter cassettes were removed immediately after the exposure period. Gauze pads were removed from their holders with solvent rinsed tweezers and placed in individual 4 ounce glass jars. Filter were sealed and replaced in their original packing containers. All samples were maintained at 4°C during shipment and storage. Samples arrived at the analytical laboratory within 6 days of collection and analyzed within the next 2 months.

Fifty mL of hexane/acetone (1/1, v/v) was added to the dermal dosimeters jars and the jars shaken for 1 hour. A 100 ：L aliquot of the extract was added to a 10 mL volumetric flask and 2 ：L of internal standard/surrogate chemical (aldrin and heptachlor, respectively). The resulting solution was brought to volume with hexane

The results of exposure monitoring are presented in Table A1.

**Table A1. Exposures of Workers Applying Lindane as a Seed Treatment at a Rate of 1.4 lb ai) Pounds of Active Ingredient per 60 Bushels of Grain (3600 lbs of seed, total. Values used for exposure estimation are in boldface.**

| Body Region | Monitor Location | Exposure (mg) | | | Exposure (mg/lb ai) | |
|---|---|---|---|---|---|---|
| | | Mean | Median | Range | Mean | Median |
| Chest | Outer | 3.21 | 2.43 | 0.92-7.84 | 2.3 | 1.7 |
| Back | Outer | 2.48 | 2.48 | 0.85-4.58 | 1.8 | 1.8 |
| Forearms | Outer | 17.75 | 15.25 | 5.57-51.79 | 13.0 | 11.0 |
| Upper arms | Outer | 4.43 | 3.88 | 0.99-10.10 | 3.2 | 2.7 |
| Upper legs | Outer | 33.96 | 20.46 | 2.90-132.55 | 24.0 | 15 |
| Lower legs | Outer | 1.34 | 9.64 | 0.43-5.95 | 0.96 | 6.9 |
| **Chest** | **Inner** | **0.45** | **0.44** | **0.07-0.71** | **0.32** | **0.31** |
| **Back** | **Inner** | **0.71** | **0.52** | **0.11-2.59** | **0.51** | **0.37** |
| **Forearms** | **Inner** | **5.43** | **3.46** | **1.31-16.70** | **3.9** | **2.5** |
| **Upper arms** | **Inner** | **1.12** | **0.79** | **0.12-2.91** | **0.80** | **0.56** |
| **Upper legs** | **Inner** | **2.88** | **2.18** | **0.08-9.32** | **2.1** | **1.6** |
| **Lower legs** | **Inner** | **0.16** | **0.12** | **0-0.33** | **0.11** | **0.086** |
| **Hands** | | **0.74** | **0.71** | **0.4-1.27** | **0.53** | **0.51** |
| **Head/Neck** | | **1.72** | **1.47** | **0.7-3.58** | **1.2** | **1.1** |
| **Total Dermal** | | **13.21** | **9.69** | | **9.4** | **7.1** |
| **Respiratory** | | **0.0022** | **0** | **0-0.016** | **0.0016** | **0** |

mg/lb ai = Exposure (mg) ÷ 1.4 lb ai

**Calculation of Daily Exposures:**

**Assumptions:**

1) An average worker weighs 70 kg and has standard body surface areas and respiration rates as presented in the Pesticide Assessment Guidelines (OPPTS 875 Group A test guidelines).

2) Examination of the Census of Agriculture data for Kansas yielded a median farm sizes of in the 100 to 249 acre range. Three other wheat producing states (North Dakota, Washington, and Montana) had median farm sizes in the 250 to 499 acre range. A farm size of 500 acres was assumed. Workers were assumed to treat and plant enough seed for 100 Acres per day, yielding a short term exposure scenario.

3) Workers are assumed to wear the same clothing as those participating in the study. Typical clothing consists of a long sleeved shirt, long pants, and chemical resistant gloves.

4) Wheat is planted at a rate of 120 pounds of seed per acre and each bushel of seed weighs 60 pounds (Hanson, A.A. (Ed) (1989) Practical Handbook of Agricultural Science. CRC Press, Inc., Boca Raton, FLA.). Therefore 2 bushels of seed would be planted per acre or 1000 bushels (120 lbs x 500 A = 60000 lbs) per farm. This is considered to be conservative since this seeding rate is primarily for winter wheat under humid conditions.

5) While the application rate varies somewhat for various types of seeds, the application rate/farm size is considered typical for lindane seed treatment products.

**Amount of seed treated per 8 hour day:**

Seed treated (lbs) = 100 A/day x 2 bushels/A x 60 lbs/Bushel = 12000 lb seed/day

**Amount of lindane handled per day:**

Lbs ai handled per day = 2 oz/bushel x 0.1875 x 200 bushels seed/day x 1 lb/16 oz

= 4.7 lbs ai/day

**Estimation of Exposure (manual seed treatment):**

**Dermal:**

Dermal Exposure (mg/kg/day) = 9.4 mg/lb ai x 4.7 lbs ai/day ÷ 70 kg x 0.1

= 0.063 mg/kg/day

**Respiratory:**

Respiratory Exposure (mg/kg/day) = 0.0016 mg/lb ai x 4.7 lbs ai/day ÷ 70 kg

= 0.00011 mg/kg/day

**The resulting Dermal MOE is**:

$MOE_D$ = 1.2 mg/kg/day ÷ 0.063 mg/kg/day = 19

**The resulting Inhalation MOE is**:

$MOE_I$ = 0.13 mg/kg/day ÷ 0.00011 mg/kg/day = 1200